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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,357	11/24/2003	Michela Gallagher	JHV-028.01	4705

25181 7590 09/21/2006

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER	
STAPLES, MARK	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,357	GALLAGHER ET AL.	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to methods of identifying a gene associated with a desired behavior or cognitive function in a mammal, classified in class 435, subclass 6.

II. Claims 7-23, drawn to methods of screening compounds for utility in promoting cognitive function, classified in classified in class 514, subclass 1.

III. Claims 24- 31, drawn to libraries comprising a plurality of cDNA, classified in class 536, subclass 23.1.

IV. Claim 32, drawn to a microarray chip comprising a solid support, classified in class 536, subclass 23.3.

V. Claims 33-36 and 33-44, drawn to pharmaceutical compositions of a compound that stimulates neural tissue, classified in class 514, subclass 1.

VI. Claim 37, drawn to pharmaceutical composition comprising heterocyclic carbon compounds with a bicyclo ring system having a six-membered two hetero ring with nitrogen and with sulfur or oxygen, as one of the cyclic compounds, classified in class 544, subclass 47.

VII. Claim 38, drawn to pharmaceutical composition comprising a single C=O group, classified in class 524, subclass 336.

VIII. Claim 39, drawn to pharmaceutical composition comprising a therapeutic agent for cognitive function and methods of administration, classified in class 514, subclass 1.

IX. Claims 40, 53, 54, and 56, drawn to methods of preserving cognitive function in a mammal in need thereof, comprising the step of stimulating, in said mammal, neural tissue expression of a glutamate transporter gene, classified in class 514, subclass 1.

X. Claims 41, 55, and 57-59, drawn to methods of treating impaired cognitive function in a mammal, comprising the step of stimulating, in said mammal, neural tissue expression of a glutamate transporter gene, classified in class 514, subclass 1.

XI. Claims 42 and 53, drawn to methods of preserving cognitive function in a mammal in need thereof, comprising the step of administering a pharmaceutical composition of claim 33 to said mammal, classified in class 514, subclass 1.

XII. Claims 43, 53, and 46, drawn to methods of preserving cognitive function in a mammal in need thereof, comprising the step of administering a pharmaceutical composition of claim 37 to said mammal, classified in class 514, subclass 1.

XIII. Claims 44 and 53, drawn to methods of preserving cognitive function in a mammal in need thereof, comprising the step of administering a pharmaceutical composition of claim 38 to said mammal, classified in class 514, subclass 1.

XIV. Claims 45 and 53, drawn to methods of preserving cognitive function in a mammal in need thereof, comprising the step of administering a pharmaceutical composition of claim 39 to said mammal, classified in class 514, subclass 1.

XV. Claims 47 and 53, drawn to methods of promoting cognitive function in a mammal in need thereof, comprising administering to said mammal an amount of a pharmaceutical composition of claim 33 sufficient to promote cognitive function selected from the group consisting of: spatial memory acquisition, long-term spatial memory and spatial memory retrieval, classified in class 514, subclass 1.

XVI. Claims 48 and 53, drawn to methods of preserving cognitive function in an aged mammal, comprising the step of administering a therapeutically effective amount of ceftriaxone or an analog or derivative thereof to said mammal, classified in class 514, subclass 1.

XVII. Claim 49, drawn to a method of treating impaired cognitive function in a mammal, comprising the step of administering a therapeutically effective amount of ceftriaxone or an analog or derivative thereof to said mammal, classified in class 514, subclass 1.

XVIII. Claims 60-62, drawn to methods of treating impaired cognitive functions comprising administering ((R)-(-)-5-methyl-1-nicotinoyl-2-pyrazoline, classified in class 514, subclass 1.

Inventions I, II, IX, X, XI, XII, XIII, XIV, XV, XVI, XVII, and XVIII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different functions. The different respective functions are mutually exclusive: I) identifying a gene, II) screening compounds, IX) preserving cognitive function by neural tissue stimulation, X) treating impaired cognitive function, XI) preserving cognitive function by administering a composition which stimulates neural tissue, XII) preserving cognitive function by administering a composition of a certain bicyclic structure, XIII) preserving cognitive function by administering a composition of a certain C=O containing structure, XIV) preserving cognitive function by administering a composition identified by a certain screening process, XV) promoting cognitive function in a mammal, XVI) preserving cognitive function in an aged mammal by administering ceftriaxone or an analog, XVII) treating impaired in an aged mammal by administering ceftriaxone or an analog, and XVIII) treating impaired cognitive functions comprising administering ((R)-(-)-5-methyl-1-nicotinoyl—2-pyrazoline Furthermore, the inventions

as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III, IV, V, VI, VII, and VIII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, differing in gross structure or molecular structure. The diffenent products are mutually exclusive: III) libraries, IV) microarray chip, V) a pharmaceutical composition that stimulates neural tissue, VI) pharmaceutical composition with a bicycle ring system, VII) pharmaceutical composition with a C=O group, and VIII) pharmaceutical composition drawn to promoting cognitive function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions III, IV, V, VI, VII, VIII and I, II, IX, X, XI, XII, XIII, XIV, XV, XVI, XVII, and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case each of the products can be used in a materially different process. Libraries can be used to screen for compounds effective in pain relief, microarray chips can be used for libraries of cDNA for screening pain relief compounds, any of the compounds might be used as an acid for cleaning, a surfactant for cleaning, an emulsifier, or molecular weight standards. None of these uses are those of processes in Groups I, II, IX, X, XI, XII, XIII, XIV, XV, XVI and XVII.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Election of Species

2. This application contains claims directed to the following patentably distinct species in Group I, II, III, V, VI, VII, IX, and X as follows.

Detection Method

microarray analysis (claims 2 and 9 in part)

in situ hybridization histochemistry (claims 2 and 9 in part)

quantitative PCR, SAGE analysis (claims 2 and 9 in part)

Northern blot analysis (claims 2 and 9 in part)

dot blot analysis (claims 2 and 9 in part)

Gene

EAAT1 (claims 5, 6, 11, 28, and 35 in part)

EAAT2 (claims 5, 6, 11, 28, and 35 in part)

EAAT3 (claims 5, 6, 11, 28, and 35 in part)

EAAT4 (claims 5, 6, 11, 28, and 35 in part)

EAAT5 (claims 5, 6, 11, 28, and 35 in part)

Cell Line

neuronal cell line (claim 17 in part)

glial cell line (claim 17 in part)

astrocyte cell line (claim 17 in part)

Claim 37

A single species of **compound** for a therapeutically effective amount must be elected from the following, according to the species in this claim:

L is O or S;

R is H, C.sub.1-10 alkyl, C.sub.1-10 alkoxy, aryl, aralkyl, --OCH.sub.2CO.sub.2H;

R.sup1. is --(CH.sub.2).sub.n--C(O)X

wherein

X is OH, NR.sub.2, SH, O-alkali metal, or

OC(CH.sub.3)OC(O)OCH(CH.sub.3).sub.2; and

n is an integer from 0 to 6 inclusive;

R.sup.2 is H, C.sub.1-10 alkyl, C.sub.2-8 alkenyl, or --(CH.sub.2).sub.a--W—R.sup.3

wherein

R.sup.3 is H, C.sub.1-10 alkyl, --C(O)C.sub.1-10 alkyl, --C(O)NR.sub.2, aryl, aralkyl, or A;

W is O, S, or NR.sup.4; and

a is an integer from 1 to 6 inclusive;

wherein

R.sup.4 is H, C.sub.1-10 alkyl, --C(O)C.sub.1-10 alkyl, aryl, aralkyl, or

R.sup.3 and R.sup.4 taken together may form an unsubstituted or substituted heteroalkyl or heteroaryl ring;

the line === indicates either a single or double bond;

R.sup.5 is R.sup.1, H, SO.sub.3H, aryl, C.sub.1-10 alkyl, aralkyl; or R.sup.5 is selected from the group consisting of .dbd.CHCH.sub.2CO.sub.2H and .dbd.NR when the line is a double bond;

m is 0 or 1; and

A is aryl or heteroaryl of formula Ia: wherein, independently for each occurrence:

J is O, S, NR.sup.6, or CR.sup.6; and

y is 1 or 2;

wherein R.sup.6 is an electron pair, H, C.sub.1-10 alkyl, C.sub.1-10 alkoxy, aryl, or --NR.sub.2; or A is heterocycloalkyl of formula Ib or Ic:

wherein, independently for each occurrence:

J is O, S, or NR; and

X is O or H.sub.2.

Claim 38

A single species of **compound** for a therapeutically effective amount must be elected from the following, according to the species in this claim:

wherein, independently for each occurrence:

X is --OH, C.sub.1-10 alkoxy, --O-alkali metal, --N(R.sup.1).sub.2, --SH, or --S--C.sub.1-10 alkyl;

R is a straight chain or branched C.sub.1-30 alkyl; and

R.sup.1 is H, C.sub.1-10 alky, C.sub.2-10 alkenyl, C.sub.2-10 alkynyl, aryl, or aralkyl;

provided that R may be unsubstituted or substituted by one or more --OH, C.sub.1-10 alkoxy, --N(R.sup.1).sub.2, --SH, --S--C.sub.1-10 alkyl, or aryl.

Claims 54, 55, 56, and 57

A single species of **compound** for a therapeutically effective amount of must be elected from the following, according to the species in these claims:

R is H, C.sub.1-10 alkyl, C.sub.2-10 alkenyl, C.sub.2-10 alkynyl, aryl, or aralkyl;

R.sup.1 is H, C.sub.1-10 alkyl, C.sub.2-10 alkenyl, C.sub.2-10 alkynyl, aryl, or aralkyl;

R.sup.2 is a hetrocyclic or heteroaryl ring comprising from 1-4 heteroatoms selected from the following: N, O, or S:

L is O, S, or NR and;

X is CR.sup.2, O, or S.

The species are independent or distinct because each species is a patentably distinct method of detection, method of gene use, method of cell line use, or compounds.

The species are independent or distinct because each method of detection is operationally different and patentably distinct, each method of gene use is operationally different and patentably distinct, each method of cell line use is operationally different and patentably distinct, and each compound is structurally different and patentably distinct

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 4, 7, 8, 10, 12-16, 18-21, 24-27, 29-34, 36, 39-53, 58-62 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

For Group I, that means applicant must elect a single specified species of acceptor, a single specified species of donor product, a single specified species of acceptor-x, a single specified species of macromolecule, a single specified species of tracer, a single specified species of catalytic activity, a single species of immunoassay, and a single specified species of fluorophore. For Group III, that means applicant must

elect a single specified species of macromolecule and a single species of fluorophore, with specification of a single derivative if elected. Specified means that a single molecule must be identified. For example, election of purified human albumin would be a single specified protein of acceptor.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these species are independent or distinct for the reasons given above and the species require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Close

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
September 15, 2006

MS

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

9/18/06